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Social impact of preventive HIV vaccine clinical trial participation: A model of prevention, assessment and intervention

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Abstract

Preventive HIV vaccine trial participants may experience problems related to trial participation, including difficulties with personal relationships, employment, education, health care, housing, health insurance, disability insurance, life insurance, travel or immigration. During the 19 years that the U.S.-based National Institute of Allergy and Infectious Diseases (NIAID) has conducted preventive HIV vaccine trials, we have developed a model to prevent and resolve social impact related to study participation and assist study participants who report such events. Key elements of the model include: informing potential volunteers of risks prior to enrollment; standardizing data collection methods on social impact events; reviewing and following-up on reported social impact events; assisting participants, including provision of free HIV testing to differentiate HIV infection from vaccine-induced HIV antibody; implementing broad-based and targeted community education programs for achieving community support; communicating with scientific and health care communities; and working with government agencies, non-government agencies and industry on mechanisms to address SI. This approach, established in collaboration with NIAID-funded clinical trial groups, serves as a model for prevention, assessment, monitoring, and intervention for social impact related to preventive HIV vaccine clinical trial participation. Although further research is necessary, this model could be adapted for use in different clinical trials.
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Keywords: Social impact; Social harm; HIV vaccine; Clinical trial; USA; NIAID

Social impact of preventive HIV vaccine trials: what are they and why do they occur?

Participants in preventive HIV vaccine clinical trials may experience problems with personal relationships, employment, education, health care, housing, health, disability or life insurance, travel and immigration. These problems are most accurately termed social impact (SI), but have also been termed HIV vaccine trial-related discrimination (Allen et al., 2001), social harms (Belshe et al., 1994; Grady, 1995) and adverse social events (Temoshok, 1994). Social impact occur for three major reasons: because family, friends and others are concerned that the investigational vaccine may be harmful to the volunteer's health; because the individual is perceived as HIV-infected or at high risk

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for HIV; or because of the repercussions of vaccine-induced HIV antibody positivity (Newman, Duan, Rudy, & Anton, 2004). Concerns may also stem from the misconception that HIV vaccines cause HIV infection, or that clinical trial volunteers are being used unethically as ''guinea pigs''. Being perceived as HIV-infected or at high risk for HIV can lead to stigmatization within the community. Any of these concerns can result in the participant experiencing domestic discord or family conflict (Paxton et al., 2005).

Vaccine-induced HIV antibody positivity is a significant concern for HIV vaccine recipients. Participants who receive vaccine, as opposed to placebo, may develop HIV antibody detectable on the standard ELISA screening tests although they are HIV-uninfected (Frey, 2003). For the majority of the dozens of vaccines evaluated by the National Institute of Allergy and Infectious Diseases (NIAID) to date, this antibody response has waned over time, and study participants have eventually tested HIV-negative. However, with a few vaccines, some individuals have remained HIV antibody positive for more than 15 years and may remain antibody positive indefinitely. For some vaccines currently in clinical trials, HIV antibody is induced in the majority of vaccine recipients, and the duration of this response is not yet known (Sullivan et al., 2006).

Management of vaccine-induced HIV seropositivity

Distinguishing between vaccine response and HIV infection in participants with vaccine-induced HIV antibody may require use of very specific commercial HIV antibody tests, Western Blot, and/or nucleic acid-based tests (NAT). Individuals with vaccine-induced HIV antibody cannot donate blood and may experience problems with health care, or difficulty obtaining health, life or disability insurance as a result of being misidentified as HIV-infected. These participants can obtain confirmatory HIV testing through the NIAID-supported HIV vaccine trial units and networks as long as they have vaccine-induced HIV antibody and remain uninfected.

Impact on clinical trial enrollment

To date, only one multi-site trial has reported on the relationship of hypothetical to actual willingness to enroll in a preventive HIV vaccine study. Among participants declining to enroll, the most commonly cited reasons were concerns in relation to time commitment of study, safety of the vaccine, and potential social harms including negative reactions of family, friends, and co-workers, as well as problems due to vaccine-induced antibody positivity. Hence social impact can pose a barrier to study enrollment (Buchbinder et al., 2004).

History of social impact in NIAID-funded preventive HIV vaccine trials

Early approach

Social impact in preventive HIV vaccine clinical trials has long been a concern. Foremost among these concerns was that individuals participating in the vaccine trial would be assumed by others to be at risk for HIV, or HIV-infected (due to vaccine-induced antibody). Hence, before the first HIV vaccine clinical trial participant was vaccinated in the late 1980s, NIAID took measures to prevent social impact and intervene when indicated. These measures included establishing a toll free number for U.S. HIV vaccine clinical trial participants to access assistance through NIAID, providing volunteers with identification cards demonstrating study participation, and performing outreach to insurance companies. However, standardized assessment of social impact was not performed for many years. Instead, reports of social impact were anecdotal.

Following recommendations from an external review of the NIAID-funded HIV vaccine networks, a standardized tool for collecting data on social impact events was developed and implemented in September 1995, and has gone through several iterations over the years. Reporting of social impact is now standard in the NIAID-sponsored HIV Vaccine Trials Network (HVTN) and Vaccine Research Center (VRC) preventive HIV vaccine clinical trials. Individual social impact events are managed on a case-by-case basis.

Building on experience

Most social impact events are foreseeable risks of study participation and are therefore addressed in protocol consent forms and discussed during the informed consent process. For HVTN preventive HIV vaccine protocols, grouped data on social impact events are posted on the password-protected network website for review by members, including Community Advisory Board representatives. Events that study participants consider as having a major impact on their quality of life are promptly communicated to the Protocol Chair. All events, regardless of type, or severity, are sent to NIAID staff on a monthly basis for review and, if indicated, follow-up. Agencies such as the U.S. FDA that